K063504

Pg. 1 of 2

MEDISPEC LTD
20401 Observation Drive, Suite 102
Germantown, MD 20876 USA
Tel: (301) 944-1575
Toll Free: (888) 6-Medispec
Fax: (301) 972-6098
E-mail: info@medispec.com

MAR 0 9 2007

510(K) SUMMARY

[21 CFR section 807.92]

Applicant's Name and Address

Medispec Ltd.
12850 Middlebrook Road, Suite 1
Germantown, MD 20874
Contact: Anil Dhingra, Vice President and COO
Phone: 301-944-1575
Fax: 301-972-6098

Date of Summary

March 2, 2007

Device Trade Name

Econolith™ EM1000

Device Generic Name

Extracorporeal Shock Wave Lithotripter

Classification Name

Class II - Lithotripter, Extracorporeal Shock Wave (Urological) [21 CFR Section 876.5990] / Product Code - LNS

Intended Use

The EM1000 is indicated for use in the non-invasive fragmentation of upper urinary tract stones, to include urinary stones located in the kidney (renal pelvis and renal calyces) and upper ureter.

Predicate Device(s)

Siemens Lithostar Lithotripter—P870018,
Dornier Compact Delta – P840008/S56, and
Medispec Econolith™ E3000 – K040461

Device Description

Medispec Ltd.'s Econolith™ EM1000 system is a transportable Electromagnetic (EM) Extracorporeal Shock Wave Lithotripter (ESWL) used for urinary stones treatment.

The EM1000 device includes a shock wave generator which is based on an Electromagnetic shock wave head and is to be used in conjunction with a multi axes Motorized Treatment Table, a C-Arm X-ray/fluoroscope imaging unit, an ECG monitor, and an anesthesia apparatus, which may be supplied by the user. The device also contains the necessary interface for optional Ultrasonic imaging devices. The EM1000 includes the following components for patient handling, positioning and shock wave generation:

- Shockwave Generator
- Electromagnetic Shock wave head,
- High-Voltage System,
- Water System,
- Treatment Table Control,
- ECG System,
- Control and Timing Circuitry, and
- Front Panel Controls

Substantial Equivalence

The Econolith™ EM1000 is substantially equivalent to the Seimens Lithostar Lithotripter (approved under PMA# P870018), the Dornier Compact Delta (approved under PMA# P8400008/S56), and Medispec Econolith™ E3000 (cleared under K040461). The EM1000 is found to be substantially equivalent to these devices in respect to the intended use, principle of operations, ancillary equipment, and technological specifications.

Technological Characteristics

All specifications are in compliance with FDA Guidance for the Content of Premarket Notifications (510(k)) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi, August 2000 and all applicable performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 0 9 2007

Ms. Sheryl D. Skinner
Manager of Regulatory Affairs
Medispec Ltd.
12850 Middlebrook Road, Suite 1
GERMANTOWN MD 20874

Re: K063504
Trade/Device Name: Econolith™ EM1000
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: March 2, 2007
Received: March 2, 2007

Dear Ms. Skinner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063504

Device Name: Econolith™ EM1000

Indications For Use: The EM1000 is indicated for use in the non-invasive fragmentation of upper urinary tract stones, to include urinary stones located in the kidney (renal pelvis and renal calyces) and upper ureter.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUING ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063504